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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/819,144

03/27/2001

Richard M. Terek

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05/16/2006

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EXAMINER

SANG, HONG

ART UNIT

PAPER NUMBER

1643

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/819,144	TEREK, RICHARD M.	
	Examiner	Art Unit	
	Hong Sang	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-10 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-10 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Terek

1. Applicant's response filed on 4/14/2006 is acknowledged. Claims 7-10 and 21-23 are pending. Claims 7, 9 and 10 are amended. New Claims 21-23 are added.
2. Claims 7-10 and 21-23 are under examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections Withdrawn

4. The objection of the specification as failing to update the first line of the specification is withdrawn in view of applicant's amendment to the specification.

Rejections Withdrawn

5. The rejections of claims 7-10 under 35 U.S.C. 112, second paragraph, as vague and indefinite for reciting the term "CSA" in claim 7 and "CSA-1" in claim 8 as the sole means of identifying the claimed molecules is withdrawn in view of applicant's amendment to the claims by including SEQ ID NO.
6. The rejection of claim 7 under 35 U.S.C. 102(e) as being anticipated by Draetta et al. (US Patent NO. 5,744,343, published on 4/28/1998, effective filing date 9/13/1994)

as evidenced by Nawa et al. (Int. J. Cancer, 1996, 69(2): 86-91) and Dobashi et al. (Diag. Mol. Path, 1993, 2(4): 257-63, IDS) is withdrawn in view of applicant's amendment to the claim by including SEQ ID NO.

7. The rejection of claim 1 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of applicants' amendment to claim 1.

Response to Arguments

8. The rejection of claims 9-10, and now amended claim 7 and new claims 21-23 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

The response states that the claims have been amended to recite an isolated CSA polypeptide comprising SEQ ID NO.2, or comprising an amino acid sequence that is at least 90% identical to the amino acid sequence of SEQ ID NO.2, wherein the polypeptide is differentially expressed in chondrosarcoma cells as compared to normal cartilage cells. The response states that a person of ordinary skill of the art, with the specification in hand and given the state of the art at the time of filing, could make and use the claimed CSA polypeptides without experimentation. Moreover, the response

states that the specification describes these CSA polypeptides in such a way as to enable one of ordinary skill in the art to make and use such molecules.

Applicant's arguments have been carefully considered but are not found persuasive. The amendment to the claims cannot overcome the rejection. The claims are not enabled because the specification fails to show that any CSA polypeptides, including SEQ ID NO.2, are in fact differentially overexpressed in chondrosarcoma cells as compared to normal cartilage cells. As indicated in the previous office action mailed on 1/18/2006, those of skill in the art, recognize that expression of mRNA, specific for a tissue type, does not necessarily correlate nor predict equivalent levels of polypeptide expression. While the specification teaches how to make the CSA polypeptides, since there is no data indicating that any CSA polypeptides, including SEQ ID NO.2, are differentially expressed in chondrosarcoma and normal cells, one skilled in the art would not know how to use the claimed CSA polypeptides. Furthermore, the claims encompass fragments and homologues that are at least 90% identical to SEQ ID NO.2. One skilled in the art would recognize that not all these protein fragments and homologues have the same functions as SEQ ID NO.2. The instant specification does not teach that these polypeptides have the same functions as SEQ ID No.2. Because of these reasons, the rejection is still proper and therefore maintained.

9. The rejection of claims 9, 10 and now new claim 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

The amendment to the claims has been described above (see paragraph 8). The response states that independent claim 9, as amended, recites an isolated CSA polypeptide that contains an amino acid sequence that is at least 90% identical to SEQ ID NO.2, wherein the polypeptide is differentially expressed in chondrosarcoma cells as compared to normal cartilage cells. The response states that the claimed polypeptides are fully described in the originally filed specification.

Applicant's arguments have been carefully considered but are not found persuasive. The amendment to claims 9 and 10 cannot overcome the instant rejection. The instant claims 9, 10 and 23 encompass a genus of polypeptides, wherein the polypeptides contain an amino acid sequence that is at least 90% identical to SEQ ID NO.2, and are differentially expressed in chondrosarcoma cells as compared to normal cartilage cells. Moreover, the instant claims also encompass fragments of SEQ ID NO.2. However, the written description in this case only sets forth one CSA polypeptide, i.e. SEQ ID NO. 2, therefore the written description is not commensurate in scope with the claims which read on any and all polypeptides that are 90% identical to SEQ ID NO.2 and are differentially expressed in chondrosarcoma and normal cells. Applicant does not appear to have reduced to practice any CSA polypeptides, any fragments or homologues of SEQ ID NO.2 except SEQ ID NO.2. Neither has applicant provided sufficient descriptive information such as definitive structural or functional features that are common to the genus of the claimed CSA polypeptides, and to the genus of the fragments and homologues of SEQ ID NO.2. Because the genus of polypeptides encompassed by the claims is extensive and the artisan would not be able

to recognize that applicant was in possession of the invention as now claimed. As such, the rejection is still deemed proper, and therefore is maintained.

Conclusion

10. No claims are allowed

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1643

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hong Sang
Art Unit 1643
Apr. 28, 2006



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER